



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 January 2026
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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Rezurock belumosudil

On 29 January 2026, the Committee for Medicinal Products for Human Use (CHMP), following a re-examination procedure, adopted a positive opinion, recommending the granting of a conditional² marketing authorisation for the medicinal product Rezurock³, intended for the treatment of chronic graft-versus-host disease (cGVHD) in last line patients, aged from 12 years of age who weigh at least 40 kg.

The applicant for this medicinal product is Sanofi Winthrop Industrie.

Rezurock will be available as 200 mg film-coated tablets. The active substance of Rezurock is belumosudil, an immunosuppressant (ATC code: L04AA48). Belumosudil is a selective Rho protein kinase 2 inhibitor, which selectively downregulates interleukin 17 and 22 (IL-17 and IL-21) secretion and mediates signalling in immune cellular function and fibrotic pathways.

Treatment with Rezurock resulted in an overall response rate of about 44% at 6 months and a median duration of response of 23.9 weeks in patients with cGVHD, in a phase 2, open-label, multicentre study. A response (defined as any response in one of the study assessments) was observed in about 73% of patients treated with Rezurock plus standard of care (such as corticosteroids, calcineurin inhibitors, sirolimus, ruxolitinib, and/or extracorporeal photopheresis). The most common side effects with Rezurock include fatigue, diarrhoea, nausea, headache, vomiting, aspartate aminotransferase (AST) increased, alanine aminotransferase (ALT) increased and gamma-glutamyltransferase (GGT) increased.

The full indication is:

Rezurock is indicated for the treatment of adults and paediatric patients (12 years and older with a body weight of at least 40 kg) with chronic graft-versus-host disease (cGVHD) when other treatment options provide limited clinical benefit, are not suitable, or have been exhausted.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.

³ This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained



Treatment with Rezurock should be initiated and supervised by physicians experienced in the treatment of cGVHD.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.